

EVALUATION OF MORBIDITY  
MORTALITY AND FAILURE RATE  
OF LAPAROSCOPIC STERILIZATION

THESIS

FOR

MASTER OF SURGERY

( OBSTETRICS & GYNAECOLOGY )

8490

BUNDELKHAND UNIVERSITY  
JHANSI (U. P.)

C E R T I F I C A T E

This is to certify that the work on "Morbidity, Mortality and failure rate of laparoscopic sterilization" which is being submitted for M.S. (Obstetrics and Gynaecology) thesis by Dr. Sushma Singh has been carried out under my personal guidance and supervision. Her observation and results have been periodically checked by me.

She has fulfilled the necessary stay in the department according to regulation of the University.

  
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C E R T I F I C A T E

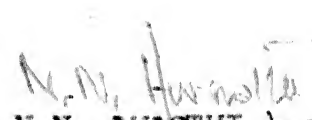
This is to certify that the work entitled  
"MORBIDITY, MORTALITY AND FAILURE RATE OF LAPAROSCOPIC  
STERILIZATION" has been carried out by Dr. Sushma Singh  
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## A C K N O W L E D G E M E N T

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Sushma Singh  
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## C O N T E N T S

	<u>PAGE NO.</u>
1. INTRODUCTION	1-3
2. REVIEW OF LITERATURE	4-40
3. MATERIAL AND METHOD	41-45
4. OBSERVATIONS	46-58
5. DISCUSSION	59-71
6. CONCLUSION	72-75
7. BIBLIOGRAPHY	I - XXIV
8. SUMMARY (Enclosed separately)	

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\* I N T R O D U C T I O N \*  
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I N T R O D U C T I O N

Sterilization is one of the oldest fertility control method, which was mentioned by Hippocrates. No single method of sterilization is probably suitable for all women.

The scarcity of our facilities and resources with the pressing problems of our increasing population demands a method of sterilization which is at once appealing and safe to the patient, capable of performance on an out patient basis in large numbers and economical to governmental or other agencies which promotes this method.

Laparoscopy, the so called 'Band-Aid Surgery' is considered as a safe and simple procedure. However as increasingly large number of patients are undergoing laparoscopy, a proportionately large number and variety of complications are being observed.

Since the introduction of mass rural laproscopic sterilization camps, the procedure has proved highly acceptable, economic, speedy and safe. To the surgeons well trained in this technique, it is a chosen due to its reliability, low failure rate, minimal complications,

speed, minimal anaesthesia required, restriction of the numbers of instruments, minimal time wastage in sterilizing the instruments, financial involvement and nominal pre and post operative care.

In camps a proper follow up of patients is essential to ascertain the incidence of complications and also the failure rate. But the task is made difficult by the wide spread scattering of patients and in the reluctance to come back to the centre for the follow up owing to preoccupation with their domestic and other duties.

In case of reported pregnancy following sterilization, care should be taken to eliminate by proper history taking and examination either a pre existing pregnancy or a luteal phase pregnancy at the time of sterilization. Patients are often ignorant of the dates of their last menstrual period or sometime deliberately give wrong dates to join priority for inclusion in the camps.

With a slightest laxity in the care and vigilance on the part of the operating team, such as failure to maintain sharpness of instruments or catheterization when necessary, the incidence of complications can increase manifold. These

include anaesthetic complications like cardiac arrest and arrhythmias, trauma to bowel, bladder and pelvic organs, haemorrhage from abdominal wall, pelvic blood vessels and tubal mesentery, pelvic side wall and ovarian vessels and mesentery of bowels.

With the proper selection of patients and technique, the incidence of such complications should be negligible.

In first week follow up patients may complaints mild to moderate pain, fever, vaginal bleeding and from stitch line slight serous discharge.

In long term follow up of cases along with explanation for subsequent pregnancies, principal reasons can be

- Luteal phase pregnancy.
- Undetected wrong application of ring.
- Incomplete luminal occlusion.

The failure following female sterilization may be due to recanalisation of the tube, formation of tubo-peritoneal fistula or operator error.

Mortality rate is negligible in most of surgery.

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 REVIEW OF LITERATURE  
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## REVIEW OF LITERATURE

The origin of laparoscopic instrumentation date to the primitive apparatus of Bozzani, developed in 1805, with which he used a candles light to visualize the human urethra.

1902 Kelling injected air into the peritoneal cavity for the first time to obtain a better view of abdominal organ at the time of endoscopy.

1912 Weber was the first to combine artificial pneumoperitoneum with roentgenographic examination.

Jacobacus in 1912 was the first to report the introduction of air to create a pneumoperitoneum in human.

Nordentoejt 1912, Palmer 1947 made a most important observation of the female genital organs after gaseous distension of the abdominal and adoption of the trendelenburg position.

1919 the method by this time was called pneumoperitoneum and was introduced into the united status by Steward and Stein.

1921 Alvarez introduced the rapidly absorbing carbondioxide gas for pneumoperitoneum.

1924 Zolllikefer give the first reference to use insufflating gas other than air. He used carbondioxide because it was more rapidly absorbed.

1926 Stein employed iodized oil to outline the uterine cavity and fallopian tubes in combination with pneumoperitoneum.

Bhatt of Baroda, has recently reported on the safe use of air insufflation in over 5000 cases of laparoscopic sterilization.

Telinde 1939 attempted endoscopy by the vaginal route in the lithotomy position. While Decker 1946 adopted genopectoral position after the induction of pneumoperitoneum.

Kelting and Zacobacus in 1952 introduced the fiberoptics which was the single most important stimulus to the evolution of modern laparoscope since then, the contribution of Palmer Frangusheim, Seem, Steptoe, Cohen and others are documented in the equipment.

1952 A.A.G.L. survey of 3,60,000 cases and Loffer and Pents review of 32,714 cases reported. The most common complication involve the creation of pneumoperitoneum and often result in failed laparoscopy. These occurred in 7.4/1000 cases. Bleeding was reported

in 5.6/1000 cases. Perforation of abdominal organs or large blood vessel by needle or trocar occurred in 2.7/1000 cases. Electrical complications can be the most serious and have been reported in 2.2/1000 cases. Injection was not as common, reported in 1.4/1000 cases. Bowel burns had been the most serious late consequence but occurred in only .5/1000 cases. Cardiac arrest was reported 10 times and was fatal in three.

No death occurred in 75,000 sterilization. Pregnancy becomes a late complication of laparoscopic sterilization in about 2.5/1000 cases.

Handly 1955 and Roddock 1957 used air for pneumoperitoneum without complications and eventually published the results of over 5000 cases of diagnostic peritoneoscopy.

Patrick Steptoe 1960 offered many advantages of abdominal approach over the vaginal route.

In 1965 the double barralled insufflation cannula was made by Verres Frangenheim which is having a spring mechanism in it which checks bowel perforation.

On the recommendation of Toyer, Rozat, he inserted verres needle at the midpoint of the lower circumference of the umbilicus as bowel is less likely to be adherent to anterior abdominal wall at this point.

Stephens in 1967 said that skinfold should not be lifted up with fingers in markedly obese patient as it tends to increase the distance between the peritoneum and skin.

A multicentric study in different medical colleges in 1967-1968, total 2296 laparoscopic ligations were done, of which six had to be completed by laparotomy. Out of these, in 1994 cases cauterization of tubes were done and in rest cases ring application was done. Following complications were noted :-

Haemorrhage	- 4 cases
Shock during pneumoperitoneum-	1
Uterine injuries	- 15
Visceral injuries	- 24/2296
a. Post partum	- 5/222 cases
b. With MTP	- 7/630 cases
c. Interval	- 12/1391 cases.

Stephens 1969 of England described cauterization of tube at two points and then dividing the tube midway between cauterized area.

Cohen 1970 popularized laparoscopy in USA brought out a manogram since then it is being widely used as a diagnostic procedure and for female sterilization.

Liston et al 1970 reported uterine perforation by manipulator in some of the cases. Out of 760 patients not requiring any surgical treatment.

He also reported 5 cases of failed pneumoperitoneum and one case of pneumobladder out of 760 patients.

Two incision technique was advocated by Steptoe and Palmer before 1971.

During a discussion at the 1971 conference on the female sterilization, Wheelless noted that hand pumping of room air was possible but air is not readily absorbed into the blood stream and caused more post operative patient discomfort than CO<sub>2</sub>.

Wheelless 1971 performed cases in local anaesthesia. He also advocated the one incision technique in which fallopian tubes were electrocoagulated but not divided and found it better than two incision technique.

In 1972 he also elected to institute a three burn and tubal transection technique because of the high failure rate of the single incision one burn technique.



Nazar of Mexico used Tanalum I cm weck hemoclip across the fallopian tube through a small colpotomy incision and transecting the fallopian tubes between these two clips. It was decided that trial should be made by applying two hemoclips to the fallopian tube without tubal transection via the laparoscopic approach.

Peterson 1971, Wheelless 1973 reported 5 cases of uterine perforation out of 168 cases and 9 cases out of 36000 cases respectively.

Peterson 1971 also reported 5 cases of failed pneumoperitoneum resulting to failed laparoscopy out of 168 cases.

Up to 1971 laparoscopic sterilization was performed under general anaesthesia and hospitalization of patients for 48-72 hours.

In 1971 a program for outpatient laparoscopic sterilization was developed at North Carolina Memorial Hospital and 129 patients were operated.

Out of these 50% had shoulder pain for 1-2 days, 35% had abdominal pain for 4-5 days and 19% had pelvic pain.

Three patients had fever for 3 days.

Paterson et al 1971, Edgerton 1973 reported that one case each of stomach perforation in their series of 168 and 1132 cases respectively.

1971 Clefford R. Wheelless performed a series of 1000 cases operated by one incision technique in which fallopian tube was electrocoagulated but not divided. Patients tolerated this procedure extremely well but there were 11 surgical failure and 5 operative errors.

Evaluation of the etiology of this excessively high failure rate revealed a significant recanalization of the fallopian tubes in the area of the electrocoagulation.

Incidence of gastrointestinal burns were same as obtained in the two incision technique.

Incidence of skin and abdominal burn were rare, only one.

Jacques E. Rioux and Diogene Cloutur performed 218 laparoscopic sterilization using either the one or two puncture approach. Of these, 45 patients were done more than two years ago and 157 cases were done more

than one year ago. There were no pregnancy and no major complications.

1971-1972 Jack P. Mercer, Jacoslar F. Hulka, John I. Fishburne, Thompu Kumarasamy had conducted a study at the University of North Carolina in Chapel Hill lead to development of the spring loaded clip to be applied to the uterine tubes through a single abdominal incision by laparoscopy.

Of a total of 200 patients, one technical failure occurred in a 209 lb patient with a thick abdominal wall in whom there were not able to maintain an open channel through the fat between the rectus and the peritoneum.

In another patient who weighed 210 pounds, pneumoperitoneum could not be induced in the usual manner.  $N_2O$  was introduced through cul-de-sac and clips were then applied through the laparoscope.

In 10 patients vasovagal reactions occurred secondary to excessive manipulation of the uterus while attempting to expose the tubes for proper visualization. Intravenous atropine was given and all but two patients improved rapidly.



One patient admitted for one week for treatment of pelvic inflammatory disease flare-up.

On followup, six patients reported fever for one day duration.

No change in menstrual pattern were apparent.

Three of these patients show failure of this procedure. On reexamination it were revealed that clip was applied either on round ligament or on mesosalpinx.

1972 Chaturachinda reported on 250 cases and one year later on a total of 800 cases of laparoscopic sterilization by electrocoagulation, in which room air was used for pneumoperitoneum without complications.

Merur et al 1972, Hulka et al 1973 and Kumar-Swamy et al 1974 published their experiences with spring loaded clips.

Another participants at the first meeting of the A.A.G.L. in 1972, Frangenheim reported on the safe use of air for peritoneoscopy.

In 1972, a survey of 7478 laparoscopic ligation in K.E.M. Hospital omental haematoma by verres needle was seen in one case which was big enough to necessitate a laparotomy for its evacuation and ligation of injured vessel.

In 1972, S.D. Shinde in her series of 7478 cases, in 5 cases during her initial experience with silastic ring, tube was transected and laparotomy were done.

Wheless and Thompson 1973 did tubal ligation with prolone loop.

1973 Jacques E. Rioux and Diogene Cloutier in a staff meeting of the Department during a discussion of our third unrecognized intestinal burn occurring during a leparoscopic sterilization the idea of a bipolar instrument was concieved using the palmer biopsy tong as a model they worked with the engineers of department and produced a first prototype made largely of nylon.

One side was done by bipolar instrument and otherside was done by the classic unipolar technique. The only difference was that on the bipolar side, the coagulation was spread into the mesosalpinx.

Thompson and Wheless in 1973 reported an incidence of (.3%) cases of gastrointestinal complications.

Hulka in 1973 introduced tubal clips sterilization method. Clips applied at right angles to the tube in the isthemic position, approximately 2 cm from uterotubal junction. There is no way to remove or change it, once

applied. This method has failed to become popular because of the high cost and significant failure both in its technical application and failure rate in sterilization (Farooqui and Bazyoli 1975).

Silastic bands were first introduced by Ban Yoon in 1973. It is a safe simple effective form of sterilization, most popular now a days. In this method, falop ring is applied on both side to a loop of fallopian tube.

Edgerton 1973 reported one case of stomach perforation by verres needle and inflation of gas into the stomach.

Peterson and Crimwade 1973, Phillips et al 1975-76, Royal College of Obstetrician and Gynaecologists 1976-77, American Association of Gynaecologists and laparoscopists survey 1977, Edgeston and Klippinger 1977, Hamburgetal 1978, George et al 1978, R.C.O.G., D.H.S.S. and Medical Defence Organization 1978, Member of Working Party of the confidential enquiry into Gynaecological laparoscopy 1978, Makanji et al 1980, Frenkel et al 1981, Shinde and Krishna 1981 reported a complication rate ranging from .22-6.4%.

Keith et al 1973 reported a case of omental protusion through the wound immediately after withdrawl

of the trocar in his series of 172 patients undergoing puerperal laparoscopic sterilization.

Chaterachinda 1973 reported two cases of perforation of uterus by manipulator having previous caessarian section out of 210 patients.

Mercer et al 1973 reported vasovagal reactions secondary to excessive manipulation of uterus while attempting to expose the tubes for proper application of the clips.

Esposito 1973 reported a case of haematoma of the sigmoid colon at the time of insertion of pneumoperitoneum needle.

Cheng CHI, Dr. P.H. Paul, I. Feldblum, MSPH reported 23,636 patients in International Fertility Research Program from collaborating international facilities from 1972 to 1978.

Total 59 patients required laparotomy for complition of the sterilization procedure.

E. Bordahl studied 71 cases of laparoscopic sterilization at the Gynaecological Department of Akershus Central Hospital during the period of May 1973 to Feb 1974.

Out of these four failure case, two skin burn cases and two anaesthetic complications were reported.

One longterm followup, one patient came with colicky pain after three months, one bothered by burn injury, one was having nightmares about anaesthesia upto six years.

October 1973 to May 1975, 567 cases were operated at Johns Hopkins Hospital. There were 18 cases of tubal transection resulting from preexisting pelvic inflammatory disease, pelvic adhesion and technical errors, a total incidence of 3.1%. Four cases were treated with ring application to the proximal and distal ends of the torn segment.

In other four cases bleeding was controlled by means of electrocoagulation.

There were two cases of application of the ring to the bowel. In one of these case, ring was removed by laparotomy. In the other case, the ring was removed by the falope ring applicator via the laparoscope.

There have been three pregnancies in this group of 567 cases, an incidence of 0.53%. In 32 cases, there was postoperative lower abdominal cramping.



In 25 of these, pain lasted for less than 24 hours, in the remaining seven cases pain lasted for more than 24 hours.

In 8 cases, the ring accidentally dropped into the pelvic cavity. Some of these rings were removed with the use of grasping forceps.

Two cases of wound infection and one incisional haematoma of the umbilicus were reported.

Stephoe 1974 has introduced a method of sterilization by means of intratubal device secured in position by clips.

Georgy et al 1974 reported two cases of bladder perforation by trocar out of 800 cases.

Cunanan 1974 reported uterine perforation during manipulation out of 439 patients when laparoscopy was combined with MTP.

1974 Preston have been reported 20-30/100000 mortality.

Loffer and Pent 1974 said that the skin fold should never be lifted upwards either with a towel clip in markedly obese patient as it tends to increase the distance between the peritoneum and the skin.

Corson in June 1974 did first case by Corson bipolar forceps. The principle here is that of the regular biopsy punch forceps so that the instrument will have the capacity to cut the tube mechanically after the coagulation. Corson had done 200 cases.

Yuze, using Corson's instrument had done 100 cases.

They reported no major complication and no pregnancies.

Norison et al 1974 reported two cases of cardiovascular collapse during laparoscopy using CO<sub>2</sub> insufflation under G.A. out of 300 cases.

Phellipse 1975 reported 15 cases of CO<sub>2</sub> embolism in one year survey.

Hulka 1974 reported one case of verres needle retroperitoneal haematoma (self limiting) out of 1000 cases.

Cunananen et al 1974 reported 1 case of omental haematoma out of 439 patients of MTP laparoscopic sterilization.

Goldrath et al 1974 reported no morbidity when laparoscopy was combined with medical termination of pregnancy.

Yoon et al 1974 reported no complication in 1000 cases undergone falope ring sterilization under local anaesthesia.

Leongetnal 1974, Sethi et al 1978 reported a complication rate of 3.1% and 1.02% when laparoscopy was combined with medical termination of pregnancy.

Kleppinger in 1975 has done over 100 cases by Kleppinger bipolar forceps made by the Wolf Company and no pregnancies or major accidents have been reported.

1975 Phillips et al have reported intra-abdominal haemorrhage in 6.4/1000 laparoscopies and 2.7/1000 viscus perforation.

Loffer and Fent 1975 have reported mostly complications, namely, the perforation of major blood vessels, intestine and sever infection by verres needle 2/1000 and 7.4/1000 cases respectively.

In Bae Yoon and Theodore M., King in 1975 had done 301 cases of laparoscopic sterilization by silicon ring in 12 months.

Among this group, two patients have been admitted for observation complications to date consists of two wound infection, six segmented dissections and one incisional haematoma of the periumbilical region.



A number of patients have experienced significant lower abdominal pain requiring medication with non-narcotic analgesics in the first two post operative days. One patient experienced abdominal cramping for five days post procedure.

Ernst G. Bartsich and Thomas F. Dillon have been reported a case of injury of superior mesenteric vein as an unusual complication of laparoscopic sterilization.

Palmer, the 'Father of Modern Gynaecologic laparoscopy' and one of the world's most experienced laparoscopists with over 30 years experience, recently reported only two major complications in 7000 of his own cases, these two were bleeding.

May 1975 - May 1976, 189 women admitted to the Materinity Hospital of EL Salvador for treatment of an inevitable or incomplete abortion underwent a curettage with laparoscopic sterilization with tubal ring.

Surgical difficulties occurred during six 3.2% of the sterilization procedure.

From April 1975 to September 1976, 149 subjects were studied at the KEM Hospital in Bombay. Tubal occlusion by tubal ring was done.

Surgical difficulty was reported for one subject in the tubal ring in whom the incision had to be extended laterally.

Commonest complaints in 6 months to one year follow up were backache 69-71%, leucorrhoea 17-22%, general weakness 30-36%, anaemia 55-61%, menstrual cycles abnormality in 4.5-15.6%.

In 0.9-8% cases menstruation were scanty in 3-7%. Menstruation were excessive, 5-6% cases ovaries were enlarged, 1-3% cases uterus or fornices were tender, 1-2% cases abdominal wall hernia were reported. Tears of the tubes occur in four cases, emphysema of the abdominal wall in one case, tuboovarian abscess in one case. The tube could not be mobilized easily because of adhesions between the tubes and other pelvic structure in two patients.

The surgeon had difficulty visualizing the tubes as a result of an enlarged uterus in four cases.

In one patient of 38 years old, laparoscopy revealed an oedematous left tube. The right tube was even more oedematous and was immobile because of adhesions. A tubal ring was applied to the left tube and electrocoagulation was elected for the right tube.

The patient was readmitted to the hospital 2 weeks later with fever. She developed a tubo-ovarian abscess and underwent a total abdominal hysterectomy and bilateral salpingo-oophorectomy 23 days after the sterilization.

Hamburg et al 1976 reported a case of perforation of urinary bladder.

In 1976 A.A.G.L. follow 76866 cases in National Survey and 77647 cases in membership survey.

Out of these three deaths were reported in National Survey and no death in membership survey.

Major complications were 235 in National Survey and 216 in membership survey.

1976 all fellows and members of the college made analysis of 29661 laparoscopic sterilization. 46.9% used electrocoagulation alone, 32.7% coagulation and cutting while 14.2% used rings or bands, 4.3% clips.

In total cases four deaths occurred one following perforation of small bowel, one after gas embolism and two after cardiac arrest.

Out of these 2.7% have tubal haemorrhage and 0.9% have side wall haemorrhage, 1.8% have bowel trauma and 0.5% have bowel burn.

A regional survey in Southeast France of 5000 laparoscopies reported by Palmer showed three deaths and several injuries with permanent disabilities.

R.C.O.G. (1976-77) survey reported a failure to achieve pneumoperitoneum in 0.4% cases. A higher volume of gas was recorded for insufflation when complications were reported. 1.8/1000 cases of bowel trauma, 3.4/1000 cases of damage to other pelvic organs were reported.

1977 Yoon et al encountered the problem of tubal resection in 53 of 2643 procedures.

Roopnarine Singh et al 1977 reported a case of trocar point perforation of small bowel in their series.

Michael et al 1977 reported uterine perforation rate to be 304/1000 cases undergone laparoscopic sterilization six or more weeks following MTP.

Fishburne 1977 reported a case of uterine perforation out of 110 laparoscopic procedure by manipulator.

Brooks P.G. Marlow 1977, Cibil 1975, Pent 1974 have cautioned for the use of laparoscope in the obese. But under local anaesthesia it is most economical for mass camps.

Semm K. 1977 has shown the closeness of aorta and other great vessels to the anterior abdominal wall, the pressing of the abdominal wall in the obese and advancing the Beckton Dickinson needle of 10 cm or 12.5 cm perpendicularly has proved absolutely safe against the possible great vessel injury.

Hasson 1977 has been advocating the routine use of his open laparoscopy technique. His series of 800 patients with only one major complication of small bowel incision is fairly impressive.

In 1977-1978 a study of 200 laparoscopic sterilization by silastic ring was made by Dr. J.K. Suchdeva, C. Rajewari, B.K. Taneja at AFMC, Pune.

Laceration of the tube with slight bleeding occurred on 3 occasions. Bleeding was insignificant and stopped spontaneously.

Perforation of the uterus occurred on three occasions during manipulation.

One patient developed wound infection which respond to antibiotics.

One patient developed pyrexia exceeding 100°F and responded to symptomatic treatment.



Prolapse of intestinal loop occurred twice. This was immediately reduced without difficulty.

11 patients complained of pain, 6 complained of pain in abdomen and 2 of them required pethidine for 24 hours. Two patients complained of shoulder pain and remaining 3 complained of pain both in abdomen and shoulder.

No failure were detected in three year followup.

From September 1977 to April 1979 Jens B. Hertz had done 116 laparoscopic sterilization with falops ring. In three years followup no pregnancies have occurred.

Bleeding from the distal site of puncture and tubal transection were the most common preoperative complications occurring in 4.4% and 3.5% respectively.

In 80 patients HSG was performed after three months, unilateral leakage was demonstrated in 6 patients, 5 of these were resterilized by minilaparotomy.

1978 Penfield gives details of one patient, where the verres needle injured the abdominal aorta and also the iliac vessels. The patients required 22 units of blood, a dacron graft on the aorta and the surgeon is facing a malpractice suit of about half a million dollars.

Penfield in 1978 mentions of a patient who developed gas embolism through a verres needle placed in the common iliac vein.

Wadhwa et al 1978 in their experience of 5266 laparoscopic procedures find the incidence of gas embolism to be extremely low.

Poliakoff et al 1978 and others reported a case of ilial application in which the misplaced ring was removed after a laparotomy.

Sethi et al 1978 reported complication rate of bowel injury to be 0.15% cases. Trocar injury to uterus in 0.10% cases and incidence of surgical emphysema in 0.33% cases.

Members of the working party 1978 reported a complication rate of bowel trauma to be 1.8/1000 cases.

McCanard Kessel 1978, Pachauri et al 1980 have been extensively documented the safety and effectiveness of tubal ring technique of tubal occlusion.

A Padama Roa 1978 reported a complication rate of 3.4 per hundred cases reduced to 0.45 per hundred cases by modifying the technique of pneumoperitoneum, premedication, local anaesthesia, position of the patient and method of identification of tube by electrocoagulation method.

RCOC Survey 1976-77, members of the working party 1978 reported cardiac arrest in 0.2/1000 cases, cardiac arrhythmias in 0.4/1000 cases and pulmonary embolism in 0.2/1000 cases.

Yoon claim that silastic ring sterilization is a safe simple and effective method of sterilization.

Injury to small bowel during trocar placement occurred in one case. This was diagnosed immediately by visualization of the bowel mucosa. As exploration with repair of the injured wall was followed by an uneventful postoperative recovery. This patient had bowels adherent to the partial peritoneum due to abdominal Koch's infection.

In 1978 Prof Pratibha R. Vaidya reported 15% patients have menorrhagia following laparoscopic sterilization.

In 1978 Richard J. Stock reported 5% patients have menorrhagia following laparoscopic sterilization.

In 1978 Chatman confirmed the efficacy and safety of silastic ring.

In a survey in 1978 to 1981 at Aurangabad Medical College two failure of laparoscopic sterilization were reported. In which fallopian ring was applied on mesosalpinx in one side.



From October 1978 to April 1979, Maria Orbelina Diaz reported 400 sterilization procedures at the Cento Medico, Institute Salvadoreno de Seguro Social, San Salvador, El Salvador.

Two series of procedures were performed, the first 100 sterilizations involved a standard laparoscopy technique, the next 300 sterilizations were accomplished by Hasson's open laparoscopy technique using the Hasson trocar and blunt cannula.

Amont the 300 open laparoscopy procedure one case 0.3% of mesosalpingeal injury without bleeding was recorded as a surgical complication.

The followup complications were two cases 0.7% of urinary tract infection and two cases 0.7% of incision inflammation that required medical treatment with only aspirin or oral penicillin.

The reported sites of pain during the standard laparoscopic procedures were pelvic 5% and shoulder 2%. The intensity of pain at these sites was reported as mild.

The sites of pain during the recovery period were reported as pelvic 88% and shoulder 3%. The pelvic pain was rated as mild by 87% of the patients and moderate by 2%. In 11% no pain were reported.

Bhatt of Baroda, has recently reported on the safe use of air insufflation in over 5000 cases of laparoscopic sterilization.

During the period 1978 to 1979 K.E.Larsen and H. Kaalund Jensen planned 189 laparoscopic sterilization by falop ring.

Out of these one case need laparotomy.

Peroperatively in 14 cases transection of tube, in 3 cases laceration of tube, were reported. There were cervical tear in 5 cases, in 9 cases misapplication of ring and in two cases ring was lost.

Postoperatively 18-24% case had abdominal pain for 24 hours.

On long term followup 6 patient complained menometrorrhagia, 19 patients had dysmenorrhoea, 9 had dyspareunia and 12 had low abdominal pain, when questionnaire about climacteric symptoms, 37 had tendency to depression, 40 patients had increased tendency to irritability and 25 patients had instances of tachycardia.

Tamaskar 1978 reported intestinal perforation and uterine haemorrhage.

In a study of 1000 cases at S.M.S. Medical College, Jaipur by Prof Shashi Ramesh, Beena Bhatnagar,

pelvic inflammatory disease were reported in 6% of postpartum and 4% of interval cases. Menstrual irregularities 5% in postpartum and 6% in interval cases. Backache 4% in postpartum and 7% in interval cases. Dyspareunia was complained of 5% in postpartum and 2% in interval cases. Psychological upset was seen in 1% cases of postpartum laparoscopic sterilization.

Not even a single failure was reported among interval cases. Among postpartum group, 1 case 0.5% had conception 6 months after laparoscopic sterilization.

Katz 1979, P. and Tance M.L. reported two cases of major vessel injury during laparoscopy.

In 1979 Dhaniram et al said Yoon ring technique was associated with few postoperative symptom and necessitated a smaller skin incision. No cutting of tube was required and therefore there was no bleeding and no raw edges of tube were left.

In 1979 the centers for Disease Control began surveillance of death attributable to laparoscopic sterilization, 29 such deaths have been identified as occurring in United States from 1977 to 1981. Of these 29 deaths, 11 followed complications of general anaesthesia, seven were due to sepsis, four were due to haemorrhage, 3 were due to myocardial infarction and four deaths were related to other causes.

Mandel and Day 1979 have reported that 75% of their cases of failure due to operator error.

67% of the pregnancies occurred within 2 years of primary sterilization and 30% pregnancies occurred between 2-4 years after primary sterilization.

Cheng Chi et al 1979-80 have reported operator error as the major reason for sterilization failure in their series and most of the failure in their series and most of the failure have been reported within 2 years.

Makanji et al 1980 reported a case of haemoperitoneum due to splenic trauma by pneumoperitoneum out of 50,000 cases.

Hertz 1980 reported one case of insufflation of air in the omentum resulting in inadequate visibility leading to laparotomy.

1980 Nidhi Sharma, Farhat Hamid carried out laparoscopic sterilization on 271 patients, of these 117 cases had MTP carried out at the same time while 154 cases underwent interval sterilization.

Out of these 4 patients had trauma to the tube, 3 had perforation of uterus during manipulation, 2 had bradycardia, 2 had haematoma, 2 needs laparotomy, 2 had postoperative vomiting. 1 had injury to ovary.

Two patients had true failure due to slip of falope ring, 2 had failure due to wrong application of falop ring and 7 had failure do to undiagnosed pregnancy at the time of laparoscopic ligation.

Krishna and Shinde et al 1980 have performed most of the laparoscopic sterilization under local anaesthesia with preoperative sedation.

He had an incidence of 2.2/1000 complication and a mortality of 20/100000.

Sachdeva et al 1981, Yoon and King 1977 reported two cases of prolapse of intestine loop, each out of 200 and 2643 cases respectively.

Shinde and Krishna 1981 reported one case of injury to small bowel by trocar out of 7476 cases and one case of extensive emphysema and one case of omental haematoma.

Bartsich et al 1981 reported an complication of injury to superior mesentric vein during trocar insertion in a case, needing laparotomy.

Chir et al 1981 reported that under International Fertility Research Program through 16 Medical Centres from 11 countries during a period of two years 10 months uterine perforation rate to be 1.6/1000 cases.



1981 a multicentre study was done and women sterilized by electrocoagulation, the tubal ring and the spring loaded clips in previous abdominal surgery and nonprevious abdominal surgery group in United States.

Statified analysis determined that the rate of surgical difficulties was significantly higher in PAS women.

Judith A. Fortney, Lynde P. Cole and Kothy I. Kennedy made a survey of 1555 cases selected from 45 centres in United States for see menstrual pattern changes after sterilization.

Out of these 5% reported irregular cycles at the time of the procedure and at followup and 81.9% reported regular cycle at both times. While 7.8% had cycle that were irregular at admission but become regular by the time of the 12 months followup, 5.3% who reported regular cycles at the time of admission were reported irregular cycles at the 12 months followup.

Pouni P., Bhiwandiwalla, Stephen D. Mumford, Paul I., Felelblem made a survey of 10,004 cases for menstrual pattern changes following laparoscopic sterilization with different occlusion technique.

The majority of women reported no menstrual changes subsequent to sterilization, from 15-79% of menstrual pattern changes seen within 6 months after ligation in women who were using oral contraceptives or IUCD at the time of sterilization.

There were no significant difference between the several occlusion technique groups.

R.Punnonen and R. Erkkola in Turku University Hospital Finland 1982 investigated late sequelae after laparoscopic, Hulka clip sterilization in 100 women with followup time of  $1\frac{1}{2}$  - 3 years.

Of these patients 18% showed menstrual disorders and one patient complained of climacteric symptoms. Increased libido was reported by 34% of the women and decreased libido by 8%.

Of the husbands libido had increased in 18% of cases, while none of them reported decreased libido. Sexual intercourse felt to be more satisfactory after sterilization by 40% of the women while the others did not find any changes.

#### Menstrual irregularities :

No changes	-	77%
Metrorrhagia	-	3%
Menorrhagia	-	5%

Irregular	-	9%
Dysmenorrhoea	-	11%
Dyspareunia	-	3%
Abdominal pain	-	17%

Riedel et al, H.H., Ahrens H. and Senn, K. have reported menopausal complaints in combination with menstrual disorders in 7.4% of the high frequency technique group and 2.8% of women sterilized by the endocoagulation technique.

With the endocoagulation technique the blood vessels and nerves of the mesosalpinx are not damaged and there is therefore no disruption of the blood supply to the ovaries occurred.

Radwanska, E., Berger G.S. and Hammond J. Suggested etiological factors of post sterilization syndrome include impaired ovarian blood supply and disturbed innervation of the tube and ovary.

Donnez J., Wauters, M. and Thomas K. have suggested that women sterilized by tubal ligation have a lower midluteal plasma progesteron level than women sterilized by Hulka clips.

Hargrove and Abraham G.E. reported that patients with the post tubal ligation syndrome had



high serum estradiol and low serum progesterone level as compared with normal controls.

Neil J.R., Nobla A.D., Hammond G.T. et al in his series, patients sterilized by laparoscopic electrical fulgurations showed a significant increase in the menstrual blood loss as compared with the controls.

Edgerton W.D. in the study after laparoscopic unipolar electrical sterilization abnormal bleeding was noted in 17% and dysmenorrhoea in 3% cases.

P.E. Bordahl, M. Solberg and H. Langengen in followup study of 216 sterilization, out of which 70 were laparoscopy ligation, 50 postabortal and 20 interval cases.

There was 3 skin burns and there were problem in induction of anaesthesia in 2 cases.

Minor complication pain, itching and discomfort of the scar predominated 3 months after surgery.

One patient was having colic pain. The impact on post operative marital life was mainly positive. 23 women expressed doubts whether sterilization had been sensible, 10 expressed real regret.

Martin Versey, George Huggins Melauma Lawless made survey of 2243 female undergo tubal sterilization in 1981 by different method of tubal occlusion.

Out of these 81 patients admitted for menstrual disorders, 22 having cervicitis, 47 undergone hysterectomy and 54 needed dilatation and cerettage.

P.E. Bordahl made a 5 years followup of tubal sterilized patients.

Out of 200 followup, 5 had been pregnant, 8 had been bothered by their scar for 2 years. The majority reported improved conjugal relations and a positive impact on marriage, 85% had told others about the sterilization.

I.Cheng Chi, Paul J. Feldblum and James Higgins showed 8 patients undergo ectopic pregnancies following electrocoagulation and following tantalum clip applied.

Yacoub et al 1982 reported a rare but potentially lithal complication of gas embolism during pneumoperitoneum with carbondioxide in which patient survived.

In 1982 Diwalkar et al shows that in big institutions where proper facilities for sterilization of instruments including pre and post operative care are available, the rate of infection following surgery as 53%.

In 1982 Sarogi et al, Shahul et al under proper facilities for sterilization of instruments, rate of infection is as low as 7-12%.

A multicentre multinational randomized study under special programs of Research Development and Research Training in human reproduction 1982 found a major complication rate 0.9%, minor complications were 6% and minor complaints were in 26.5% cases.

Dr. Praveen Mehta 1982 performed laparoscopic sterilization in obese women without any major complication.

In 1982 V.R. Balmur and M.P. Bhatt reported a case of unilateral tuboovarian abscess following laparoscopic sterilization with silastic ring. Abscess developed after 23 days.

1982 Dr. V. Padubidri reported a case of fimbrial pregnancy as an rare complication of laparoscopic sterilization.

Lavinson et al reported one patient who developed bilateral tuboovarian abscess amongs 280 cases of laparoscopic sterilization.

V.R. Balmer have reported a case of septic peritonitis who had undergone laparoscopic sterilization 10 days back.

Kumar Swamy and Hurt noted the development of acute pelvic infection or tuboovarian abscess each in 1 patient among 202 women who had undergone laparoscopic sterilization and the both tubes had been transected.

Larsen and Jensen 1983 reported 5 cases of cervical tear by putting of the forceps on the cervix during manipulation out of 169 cases including interval and postabortal cases.

0.5% cases requiring laparotomy.

In a survey in Bikaner district 3000 cases were done.

In present study 2 paparotomies were performed for bleeding from mesosalpinx and in 2 cases, there was failure to perform laparoscopic sterilization.

Slight bleeding occured in 60 cases, which managed by application of another one or two rings.

There was no major complications. Pain during operation was complained by 968 women.

Post operative complications during first week was pyrexia occurred for a day or two in 385 women, vomiting by 120 women serous discharge from stitch line was present in 20.7% cases. Pelvic pain was complained by 5% of the cases, vaginal bleeding for first 24 to 48 hours occurred in 30% of cases.

As late complication, one woman developed bilateral tuboovarian mass.

Pregnancy occurred in 6 women during followup.

No menstrual, sexual or psychosomatic change had been found in any women.

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 \*\* MATERIAL AND METHOD \*\*  
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The following experiments were performed:

- Blood - serum, erythrocytes
- Urine - albumin, urea
- Hydrolysis susceptibility
- Free amylase



## M A T E R I A L   A N D   M E T H O D

The study was carried out in operation theatre at M.L.B. Medical College Hospital, Jhansi as well as in rural camps during May, 1984 to April, 1985 to evaluate the morbidity, mortality and failure rate in cases undergoing laparoscopic sterilization.

### S E L E C T I O N   O F   T H E   C A S E S

The criteria of selection of the cases was based on voluntary and motivational basis. It is desirable to exclude women who are either pregnant or puerperal.

The selection consisted of elaboration of obstetric and menstrual history and exclusion of any adverse conditions. All the patients must be admitted on the previous night and a thorough general examination, per vaginal examination and following investigations were performed.

- Blood - Hb%, T.L.C., D.L.C.
- Urine - Albumin, Sugar.
- Xylocain sensitivity.
- S.P. sensitivity.



### PREOPERATIVE PREPARATION AND PREMEDICATION

The patient are kept nil orally for at least eight hours preoperatively and an enema is given early morning. Abdominal and vaginal part is prepared and cleaned with savlon and mercurochrom lotion. Just before the procedure, they are made to void urine.

Most of the patients were given sedation as premedication, in which

- Inj Fortwin 2 amp / I.M. given
- Inj Phenargan 75 mg/I.M. given

Inj Atropine 1 amp I.M. half an hour before is given to prevent vasovagal shock and reflex brady cardia and cardiac arrhythmias.

Xylocain was injected as local anaesthesia at the site prior to the procedure. It was given subcutaneously and deep to the peritoneum subumbilically about 5-10 ml. This site is preferred because it has minimal risk of rupturing large blood vessels and it also reduces the possibility of bowel injury since the intestine is only adjacent to the site of the abdominal wall at this sites in a very few cases.

## TECHNIQUE

About half an hour after premedication patient was put in the lithotomy position on the table with a 45° trendlenburg.

Abdomen and perineum was painted with antiseptic solution (Sevlon, spirit) and draped.

An transvers one inch long skin incision was made along the lower edge of the umbilicus. Abdominal wall below the incision line was lifted up with left hand between thumb and fingers and with the right hand verres needle was inserted into the abdominal cavity directing towards pelvic cavity. Confirmation of the correct placement of needle was done by free movement of needle towards the both iliac fossa. Insufflation was done by introducing 1-1½ litre of air into the peritoneal cavity by connecting verres needle with insufflator. As air entered into peritoneal cavity, globular and symmetrical distension of abdominal wall occurred. Abdominal pressure was maintained between 10-20mm of Hg. This all procedure is known as pneumoperitoneum.

After pneumoperitoneum, verres needle was removed. Now abdominal wall was lifted up with the help of left hand on one side and another assistant

can lift the abdominal wall on otherside. Trocar was inserted with rotatory movement into the peritoneal cavity directed towards the pelvis at about  $45^{\circ}$  angle from the abdominal wall below the umblicus. It's position inside peritoneal cavity was confirmed by its free movement in all directions.

In the mean time, this was accompanied by manipulating the uterus with volsellum and manipulator inserted into the uterus. Now trocar was removed quickly and cannula was left in place and replaced by laparoscope and ring applicator loaded with falope ring.

Fallopian tube of one side first visualised, the grasping forceps was moved out from the inner cylinder, and fallopian tube was grasped. Care was taken to catch full thickness of tubal lumen. Prongs were then drawn into inner cylinder and laparoscope was slowly moved forward. Ring was applied at thinnest position of fallopian tube about 3 cm away from uterotubal junction. Then prongs were moved forward and loop of fallôpian tube with silastic ring was replaced. Same procedure was done on other side of fallopian tube. Pelvic cavity was visualized for complete haemostasis.

Laparoscope was with drawn, air was removed from peritoneal cavity, trocar was put inside the canula and whole trocar with canula withdrawn. A single deep catgut mattress suture was applied on the skin and dressed with bandaid. Antibiotic along with sedation was given post-operatively.

These patient are called on 7th post-operative day to remove stitch. Patients are follow up for immediate and late complications and failure in hospital. PHC or through house hold visits through ANM.

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 \* O B S E R V A T I O N S \*  
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Station	Observer	Time	Temp	Wind	Clouds	Humidity	Pressure	Remarks
Albuquerque	37	3.5	44	2	0	85	1	4.4
El Paso	33	3.2	-	-	-	82	84	3.3
El Paso	33	3.3	31	2	7.0	81	87	3.3

# OBSERVATIONS

This study was conducted amongst 517 cases at M.L.B. Medical College Hospital, Jhansi as well as in rural camps. held from time to time in different rural areas during May 1984 to April 1985 to evaluate the morbidity, mortality and failure rate in cases undergoing laparoscopic sterilization. 452 cases were operated in rural camp setting. They were all interval cases. While 65 cases were subjected to laparoscopic ligation in post partum theatre. They were 37 interval cases and 28 cases of <sup>MTP</sup> laparoscopic sterilization and <sup>morbidity mortality</sup> failure rate were studied in both the groups. Following observations were recorded :-

TABLE NO. 1

Showing distribution of cases in relation to camps and hospital.

Place	Interval cases			Lap.with MTP			Total		
	Total cases (a)	Study group (c)	Per-centage	Total cases (b)	Study group (d)	Per-centage	Total cases (a+b)	Study group (c+d)	Per-centage
Hospital	37	1	2.6	28	2	7.0	65	3	4.6
Camps	452	24	5.3	-	-	-	452	24	5.3
Total	489	25	5.3	28	2	7.0	517	27	5.2



Table No. 1 shows the distribution of cases having morbidity, in camps and hospital. In hospital complications occurred in 4.6% cases including cases with or without MTP laparoscopic ligation while it occurred in 5.3% cases in camps including all interval cases. No MTP were done in camps because of insufficient facilities.

TABLE NO. 2

Showing urban and rural distribution of cases.

Population	CAMPS			HOSPITAL			TOTAL		
	Total cases (a)	Study group (c)	Percentage	Total cases (b)	Study group (d)	Percentage	Total cases (a+b)	Study group (c+d)	Percentage
Urban	-	-	-	20	1	5.0	20	1	5.0
Rural	452	24	5.3	45	2	4.4	497	26	5.2
Total	452	24	5.3	65	3	4.6	517	27	5.2

Table No. 2 shows the areawise distribution of cases. It shows that in hospital cases complication occurred in 26 cases in rural and in one case (5%) in urban population, it shows more complications in rural group. In total number of cases, rural population showed complication rate of 5.2% when urban cases had 5% complication rate.



TABLE NO. 3

Showing distribution of cases according to age.

Age	CAMPS			HOSPITAL			TOTAL		
	Total cases (a)	Study group (c)	Per-centage	Total cases (b)	Study group (d)	Per-centage	Total cases (a+b)	Study group (c+d)	Per-centage
20-24	65	2	3.00	8	-	-	73	2	2.73
25-29	206	15	7.2	22	1	4.5	228	16	3.5
30-34	147	4	3.0	26	2	7.6	173	6	3.4
35-39	27	2	7.0	7	-	-	34	2	5.8
40 on-wards	7	1	14.0	2	-	-	9	1	11.2
Total	452	24	5.3	65	3	4.6	517	27	5.2

Table No. 3 shows the complication rate in different age groups of the population in camps and hospital settings. Maximum number of complications occurred in the age group of 40 onwards years while minimum number of complications were observed in the age group of 20-24 years. Complication rate in total number of cases was found to be 11.2% with 40 years onward age group while it was 2.73% in 20-24 years age group.

TABLE NO. 4

Showing distribution of cases according to parity.

PARITY	CAMPS			HOSPITAL			TOTAL		
	Total cases (a)	Study group (c)	Per-centage	Total cases (b)	Study group (d)	Per-centage	Total cases (a+b)	Study group (c+d)	Per-centage
2	63	-	-	5	-	-	68	-	-
3	151	3	1.98	24	-	-	175	3	1.7
4	147	6	4.08	20	2	10.0	167	8	4.8
5 or more than	91	15	16.48	16	1	6.2	107	16	9.5
Total	452	24	5.3	65	3	4.6	517	27	5.2

When the correlation of parity and complication rate were studied, complication rate was found to be highest with 5 or more parity that is 15 cases in camps and 1 case in hospital. Complications were NIL with parity 2 & 3 in hospital cases. Complication rate in total number of cases was 9.5% in cases with parity 5 or more than this.

TABLE NO. 5

Showing distribution of cases in relation to interval with MTP cases.

CASES	CAMPS			HOSPITAL			TOTAL		
	Total cases (a)	Study group (c)	Per-centage	Total cases (b)	Study group (d)	Per-centage	Total cases (a+b)	Study group (c+d)	Per-centage
Interval cases	452	24	5.3	37	1	1.7	489	25	5.1
Laparo-scopy with MTP	-	-	-	28	2	7.1	28	2	7.1
Total	452	24	5.3	65	3	4.6	517	27	5.2

Table No. 5 shows distribution of cases in relation to interval with MTP cases. In camps all were interval case due to lack of facilities of MTP in rural areas, while in hospital case complication rate was 7.1% in laparoscopy with MTP and 1.7% in interval cases.

TABLE NO. 6

Showing anaesthetic complications in camp and hospital setting.

	<u>CAMP</u>		<u>HOSPITAL</u>		<u>TOTAL</u>	
	No.	%	No.	%	No.	%
1. Allergic reaction	2	0.44	-	-	2	0.44
2. Shock	-	-	-	-	-	-
3. Cardiac arrest	-	-	-	-	-	-
4. Respiratory arrest	-	-	-	-	-	-
5. Pulmonary collapse	-	-	-	-	-	-
6. Apnoea	-	-	-	-	-	-
7. Nausea & vomiting	6	1.3	1	1.5	7	1.3
8. Death	-	-	-	-	-	-

Table No. 6 showing anaesthetic complications in camp and hospital setting. All cases were done under sedation and local anaesthesia (Xylocain 1%). In camp setting 2 cases were having allergic reaction to local anaesthesia. It was not sure whether sensitivity were done preoperatively or not. Inj Avil lamp I M and Inj Decadron 2 cc/IM/given state. Patients were well postoperatively.

In camp six patients and in hospital one patient were having vomiting postoperatively which respond to antiemetics.

No major complication or death were observed during survey.

TABLE NO. 7

Showing intraoperative complications in camps and hospital.

	CAMP		HOSPITAL				TOTAL	
	Interval		Interval		With MTP			
	No.	%	No.	%	No.	%	No.	%
	(452)		(37)		(28)		(517)	
1. Subcutaneous emphysema	2	0.44	-	-	-	-	2	0.3
2. Pneumo omentum	-	-	-	-	-	-	-	-
3. Pneumobladder	-	-	-	-	-	-	-	-
4. Pneumouterus	-	-	-	-	-	-	-	-
5. Haemorrhage	1	0.22	-	-	-	-	1	0.18
6. Haematoma	-	-	-	-	-	-	-	-
7. Injury to uterus	1	0.22	-	-	-	-	1	0.18
8. Injury to cervix	1	0.22	-	-	-	-	1	0.18
9. Injury to bladder	-	-	-	-	-	-	-	-
10. Injury to intestine	-	-	-	-	-	-	-	-
11. Injury to tube	3	0.66	-	-	1	3.5	4	0.7
12. Injury to mesosalpinx	1	0.22	-	-	1	3.5	2	0.3
13. Failed attempt	3	0.66	-	-	-	-	3	0.5
14. Omental prolapse	-	-	-	-	-	-	-	-
15. Extraperitoneal insertion of trocar.	2	0.44	-	-	-	-	2	0.3
16. Adhesions of pelvic organ	3	0.66	-	-	-	-	3	0.5
17. Coverage of tube with omentum	2	0.44	-	-	-	-	2	0.3
18. Misapplication of ring	2	0.44	-	-	-	-	2	0.3
19. Thickened tubes need 7 1 ring	4	0.88	1	-	-	-	4	0.7
20. Laparotomies	-	-	1	2.6	-	-	1	0.18
Total	24		1		2		27	5.2



Table No. 7 shows variety of intraoperative complications in camps and hospital cases. Only few complications were encountered in hospital but total percentage was high because that were associated with MTP. While in camps, they all were the interval cases.

Total complications rate was 5.2% in which camp cases had complication rate 5.3% and hospital cases had complication rate 4.6%.

Subcutaneous emphysema occurred in two cases in camps due to wrong direction of verres needle while no such complication occurred in hospital cases.

One of the case in camp had abnormal bleeding due to injury in mesosalpinx. But it was not much more and patient kept under observation. One case was encountered in hospital which was followed by MTP.

In one postpartum case in camp setting uterine perforation took place due to uterine manipulation. Manipulator was immediately put out and patient kept under observation and conservative treatment.

Cervical injury occurred in one case in camp setting while holding the cervix with volbellum. Cervix was hypertrophied badly eroded.

Injury to fallopian tube occurred in 3 cases in camp setting but none of them needed laparotomy. An extra ring was

applied in all cases at both teared ends and bleeding stopped. In hospital setting injury to fallopian tube occurred in one case of MTP ligation. Tube was quite thickened oedematous.

In camp setting there were three cases in which one or both tubes can not ligated. In first case patient was having previous history of convulsions. After first tube ring applied, patient was having marked fits so second tube could not ligated. In second case due to marked adhesions, left side tube could not ligated. In third case patient came after taking full diet so bowel and omentum were so distended, that both tubes could not visualized even after marked trial.

In camp setting, in two cases trocar was inserted extra peritoneally. Trocar was put out and reinserted in both cases and then sterilization done normally.

In three cases patients were having marked adhesions, out of three cases, one case postponed immediately with anti-tubercular treatment. In second and third case rings were applied with difficulty.

In two cases tubes were covered completely with omentum and rings were applied with difficulty after repeated manipulation and change of posture.

In two cases ring was applied on round ligament by junior doctor but during recheck by senior surgeon other ring applied on tube.



In 4 cases tubes were quite thick in camp setting. Out of these 3 were post partum cases and 4th one was interval case. During first attempt of ring application complete lumen did not come and second ring were applied.

In hospital setting one case were having marked bleeding and laparotomy needed. It was done by some nonexperience surgeon.

TABLE NO. 8

Showing post operative complications immediate(1st week)

	CAMP		HOSPITAL		TOTAL	
	No.in	%	No.in	%	No.in	%
	452		65		515	
	cases		cases		cases	
1. Abdominal pain (mild to moderate)	54	11.9	3	4.6	57	11.0
2. Fever	15	3.3	-	-	15	2.9
3. Serious discharge & wound infection	20	4.4	-	-	20	3.8
4. Vaginal bleeding	4	0.8	-	-	4	0.7
5. Pelvic pain	10	2.2	-	-	10	1.9

Table No. 8 shows immediate post operative complications followed within first week post operatively.

In camp setting 54 patients complained mild to moderate abdominal pain which respond to anti-inflammatory analgesics. In hospital setting 3 patient came with abdominal pain which respond to treatment.

In camp setting 15 patient came with mild to moderate fever which responded to antipyretic. Twenty cases had history of serious discharge from stitch line in camps setting and 2 cases in hospital setting which needed only local dressing.

In camp setting, four patients gave history of vaginal bleeding post operatively and 10 patients gave history of pelvic pain which respond to treatment.

TABLE NO. 9

Showing late complications in camp and hospital settings.

	CAMP		HOSPITAL		TOTAL	
	No. in	%	No. in	%	No. in	%
	452		65		517	
	cases		cases		cases	
1. Stitch abscess	5	1.1	1	1.5	6	1.1
2. Incisional hernia	-	-	-	-	-	-
3. Menstrual irregularities :-						
- Dysmenorrhoea	20	4.4	2	3.1	22	4.2
- Short cycle	24	5.3	1	1.5	25	5.3
- Long cycle	13	2.8	-	-	13	2.5
- Menorrhagia	10	2.2	1	1.5	11	2.1
- Olegomenorrhoea	11	2.4	-	-	11	2.1
- No change	274	82.8	61	9.4	435	84.2
3. Dyspareunia	10	2.1	1	1.5	11	2.1
4. Backache	55	12.1	6	9.2	61	10.1
5. Sexual disturbances	-	-	-	-	-	-
6. Psychosomatic changes	-	-	-	-	-	-
7. Bilateral tubo-ovarian mass	-	-	-	-	-	-

Table No. 9 showing late complications in camps & hospital cases.

Five cases of camp and one case of hospital ligation came with stitch line abscess which respond to local dressing along with antibiotics.

On long term followup of camp cases, 20 patients gave history of dysmenorrhoea, 24 of short cycle, 13 of long cycle, 10 of menorrhagia and 11 of oligomenorrhoea.

In hospital cases 2 patients came with history of dysmenorrhoea, one with short cycle and 1 with menorrhagia.

10 patients gave history of dyspareunia in camp cases and one in hospital case.

55 patients came with history of backache in camp cases and 6 in hospital cases. Most of them had previous history of backache.

All these cases responded to symptomatic treatments and none of them needed hospitalization.

TABLE NO. 10

Showing failure rate in camps and hospital cases.

	<u>CAMP</u>		<u>HOSPITAL</u>		<u>TOTAL</u>	
	No.in	%	No.in	%	No.in	%
	452		65		517	
	cases		cases		cases	
1. Failure due to slip of falope ring or misapplication.	-	-	-	-	-	-
2. Failure due to undiagnosed pregnancy attime of ligation.	2	0.44	-	-	2	0.36
3. Luteal phase pregnancy	1	0.20	-	-	1	0.19

Table No. 10 shows failure rate in camps and hospital cases. In camp cases, three patients came with history of amenorrhoea.

Out of these, 1st patient had history of amenorrhoea, 2 months at the time of operation and IIInd patient had history of amenorrhoea - one month 20 days. This undiagnosed pregnancies were continued and patient came at 5 months and 6th month of pregnancy for termination respectively.

IIIrd patient gave menstrual history during operation that period is to be come within 2-3 days. On per vaginal examination uterus was normal size. Pregnancy was continued in same cycle.

So no actual failure was recorded in this followup.

Mortality rate was NIL in our study.

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\* D I S C U S S I O N \*  
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## DISCUSSION

In the present work, an attempt has been made to study morbidity, mortality and failure rate of laparoscopic sterilization. The study was conducted in rural camps as well as in post partum theatre of M.L.B. Medical College, Jhansi.

In this study total 517 cases were subjected for laparoscopic sterilization by silicone ring. Out of these 452 cases were done in camps and all of them were interval cases. 65 cases were done in post partum O.T. of this hospital. Out of these 37 were interval cases and 28 were M.T.P. laparoscopic sterilization. No case of M.T.P. sterilization was done in camps due to lack of proper facilities.

It is evident from table No.1 that complication rate in interval cases in hospital and camps differs very much. In hospital, rate was 2.6% while it was 5.3% in camps cases. The reason behind this was that no good facilities available at camps and most of camps are target oriented and time limited programmes. While in hospital case, full facilities are available and team is not in hurry.



In camps, cases are not selected properly and neither prepared properly. Many times, they are not investigated, history is not taken properly. Some times they enter in operation theatre without per vaginal examination, without bowel and bladder evacuated. All these factors cause much more complication rate in camps in comparison to hospital cases.

When we studied area wise distribution of cases, we found that complication rates are much more in rural population as compared to urban. This is attributed to the fact that rural population differs from the urban in being of a lower socioeconomic and low education status, poorer personal hygiene. They are usually malnourished, under weight, have skin infection, laxity of abdomen and divarication of recti. In present study urban population show complication rate 5% and rural population shows 5.2%.

Table No. 3 and 4 shows age parity wise relation to complication of sterilization. It was seen that complication rate increases with increasing age and parity. The reason behind this was that all above factors contributed to increased operative risk. Women having these factors are usually of low socioeconomic group with poor personal hygiene, malnourished, under weight, skin, diseases, laxity of abdominal wall.

As shown in Table No.5 complications were correlated with interval cases and with M.T.P. cases. In camps only interval cases operated due to lack of proper facilities. While in hospital both interval as well as with MT.P. cases were operated. It was shown that complication rate was more in cases with M.T.P. as compare to interval cases due to softness of uterus. The complication rate were 5.3% in interval cases in camps while in hospital setting it was 2.6% in interval cases and 2.7% in cases with M.T.P. Tubes of pregnant uterus were soft, oedematous and hyperemic so they got turned during procedure easily. This study was in accordance with Cunanyan and Coverg (1974), Leong et al 1974, Hernandez et al 1977, Baggish et al (1979). While Chamlerlain (1973) and Larsen and Lensen (1983) have not shown any correlation between interval and M.T.P. laparoscopic ligation.

As shown in Table No.6 anaesthetic complications were very few. In compare to hospital cases, allergic reaction were more in camp cases as no xylocain sensitivity were done preoperatively in all cases.

Table No.7 shows various types of complication in camp setting and hospital setting. In camp 24 complications were noticed in this study but all were of minor, complications and did not needed any specific treatment.

Complication like subcutaneous emphysema occurred in 0.44% cases which was created by junior staff. However mistake was diagnosed immediately. No other complication like pneumobladder, pneumouterus were noticed as reported by Liston et al (1971), Sethi et al 1978 and Shinde and Krishna 1981.

No cases of omental prolapse were seen as reported by Yoon and Kind 1977 in 0.07% and Suchdeva et al in (1981) 1% case.

One of the case in camp setting had much more bleeding from skin incision. Deep skin incision given by one of junior doctor which had some bleeder. Deep 3 catgut suture given and kept it pressed. Bleeding stopped within sometime.

As shown in Table No. 7, uterine perforation occurred in one case (0.22%) due to excessive manipulation by manipulator in camp setting. This was in consistent with the study of Clifford et al (1973) 0.25%, Liston et al 1976, Sethi et al (1978) .72%, Suchdeva et al (1981) 1.9%. I.C.M.R. (1982) 0.57%.

In different studies uterine perforation were more found in cases with medical termination of pregnancy due to soft uterus and manipulation by dilator. But in our study we did not go through this complication in hospital cases.

In one of the case injury occurred in cervix while holding it with volsellum. Cervix was hypertrophied and had bad cervix erosion. Bleeding started but it stopped by tight packing.

In our present study no case of trocar injury or to bowel occurred as it was reported by Thompson and Wheelen (1973) in 0.3%, Roopnarine Singh et al (1976), Sethi et al (1976) in 0.15%, Shinde and Krishina (1981) in 0.01% and by ICMR (1982) in 6.5% cases. Similarly injury to stomach by trocar was reported by Endgerton in (1972) in 0.1% and by Peterson et al (1976) in 0.59% cases. Injury to spleen was also reported by Endgerton in 1972. But no such complications occurred in our series.

No case of bladder injury was reported in our series of total 517 cases as reported by Georgy et al (1974), Hamburg et al (1978) and Phillips (1980).

No case of injury to uterus by trocar was reported in our series as reported by ICMR in 1982.

Injury to mesosalpinx occurred in one of the camp cases and one of the hospital case. In camp case patient was having lots of adhesion. As tube along with mesosalpinx is held by prongs, bleeding started.

In our study injury to tubes occurred in 3 camp cases (0.66%). In two cases tube was fixed in position

and as it was pulled by prongs, tear occurred. In third case, as tube was caught by prongs uterus was manipulated on opposite side suddenly, this led to tear in tube.

In hospital cases, in a case of M.T.P. lap ligation, tube was soft oedematous, got teared during pull by prongs. This study was in accordance with Sethi et al (1978) while higher incidence was recorded by Yoon and King (1973-75) in 1.9%. Levinson (1976) in 1.46% cases, Chatman (1978), Suchdeva et al (1981) 1.5%, Shashi Gulati and Vandana Agarwal (1981) in 2% cases.

In our study high rate of tubal transection reported in M.T.P. cases 3.5% as also reported by Larsen and Jensen (1982) in 7% cases.

In our study there were three cases in camp setting 0.66% in which one or both tubes could not be ligated.

One patient 0.22% had convulsion on the table after one tube ligated. Patient was having previous history of epileptic fits which was hidden by her relatives previously.

In 2nd case (0.22%) due to marked adhesion, left tube could not be ligated. In third case 0.22% patient came after taking full diet so bowel and omentum were so distended that both tubes could not be visualized.



even after marked trial. Chatman (1978) reported in 0.82% cases where he failed to apply ring over the tubes. This problem did not come much more in our study as most of the procedure was done by senior person.

In our study, we faced problem in visualising tubes in 3 cases due to pelvic adhesions, so tubes were ligated with some difficulty. Same problem was reported by Levison et al (1976) in 5.35%, Hertz (1980) 3.75%, Shashi Gulati and Vandana Agarwal (1981) 0.25% cases, Muthcontre, Meethnational randomized study (1982) in 0.48% cases.

In two cases 0.44% omentum was covering the tubes and uterus but tubes can be visualized after marked attempt.

In 2 cases in camp setting 0.44% ring was applied on round ligament by some of junior doctor but it was checked by senior surgeon and other ring applied on fallopian tube. Since all the cases were checked by senior surgeon so they could be detected in time same incidence was reported by Levinson et al (1976) 0.7% and Chatman (1976) 1.2%. High incidence were reported by Shashi Gulati and Vandana Agarwal (1981) 6% cases, Suchdeva et al (1981) 2%, Larsen and Jensen (1983) in 4% cases.



Sometimes ring slip in abdominal cavity by junior staff. It was also reported by Chatman (1978) in 2% and Shashi Gulati and Vandana Agarwal (1981).

In 4 camp cases (0.88%) tubes were thickened oedematous and in 1st attempt of ring application lumen were not covered completely by junior staff so second ring were applied again by senior surgeon. Higher incidence was given by Levinson et al (1976) in 3.2% cases and Suchdeva et al (1981) in 2% cases.

In hospital setting one case had marked bleeding and site of bleeding can not visualized so it needed laparotomy. But that case was started by some nonexperienced surgeon.

No case of omental haematoma was reported in our series as reported by S.D. Shinde and U.R. Krishna (1978) in one case.

(1978-79) No case of major vessel injury were reported in our series as reported by Penfield (1978) in one case.

Wadhwa et al in 1978 reported a case of gas embolism and Hassen in 1977 reported a case of small bowel incision out of 800 cases but none of this type of complications were reported in our cases.

In our study no ring were applied on small bowel as reported in Poliakoll et al (1978) in his study.

In our study one major complication were reported which were done by some unexperienced surgeon who were undertraining, in that case laparotomy need. Except this, by senior surgeon no major complications were reported. While 2.2% per 1000 case of major complications were reported by S.D. Shinde and U.R. Krishna in their study, Edgerton and Kleppinger reported 5.9/1000 cases of major complications needed laparotomy.

No case of shoulder pain was observed in our study as reported by Suchdeva et al (1981) in 1% case.

No mortality occurred in present study as it was reported by Endgerton and Kleppinger (1973) 0.013%, A.A.G.L. Survey (1975-76) 0.0026%, Chamberlain et al (1976-77) 0.008-01%, Shinde and Krishna (1981) in 0.026% cases.

In this study about 11% patients showed mild to moderate abdominal pain on 1st and 2nd day post operatively which respond to analgesics and sedation. These pains are probably caused by ischemia resulting from the occlusion of the blood vessel in ligated tubal

sling. Same was reported by Shashi Gulati and Vandana Agarwal (1981) in 428% cases, Suchdeva (1981) in 7% cases, Saroj & Jyotasana (1984) in 32.26%.

2.9% patient complained of mild to moderate pyrexia for which no cause could be found. Pyrexia settled down with symptomatic treatment. Suchdeva in 1980 reported pyrexia of unknown origin in 0.5% cases. Shashi and Vandana reported fever mild to moderate (1981) in 79% to 2.4%, Saroj and Jyotasana (1984) in 13% cases.

In our study mild to moderate vaginal bleeding were complained by 4 cases (18%) in first 24 to 48 hours. It was also reported by Shashi and Vandana (1981) in 20-24% cases, Tanwar and Jyotasana in 30% cases.

As table shows 20 patients (4.4%) complained of serious discharge from the stitch line. Which needs only dressing. This was also reported by Shashi and Vandana (1981) in 1.4% cases, Tanwar and Jyotasana in 20% cases.

Pelvic pain was complained by 2.2% cases in our study. It is also reported by Tanwar and Jyotasana (1984) in 5% cases.

In very few cases (1%) patient developed stitch line abscess which respond to antibiotics and local dressing. This is because most of rural patient have very poor hygiene.

On long term followup, none of patient developed tuboovarian abscess as reported by Tanwar and Jyotasana (1984) in 1 case, Hoover (1979) in one case.

The majority of women reported no menstrual changes subsequent to sterilization. In our study 16% patient have menstrual irregularity but most of them had previous history of menstrual disturbances also.

K.E. Larsen and H. Kalrid Jensen (1978-1979) reported gynecometrorrhagia in 3%, dysmenorrhoea in 10%. Prof. Shastri reported menstrual irregularities 5% in post partum and 6% in interval cases, Pounip, Bhiwandiwalla, Stephen D., Memford, reported 15-79% menstrual pattern changes within 6 months after ligation. R. Punnonen and R. Erkkola reported 18% patients show menstrual changes. Riedel et al reported 7.4% menstrual disorders.

In our study 2.1% reported dyspareunia while Larsen and Jensen reported in 47% (1978-1979), Shashi and Beena (1979) reported in 2-5% cases.

Bachache was complained by 10% cases in our study, while Larsen reported in 6% and Shashi reported in 4% cases.

No sexual disturbances and psychological changes reported in our study.

In our study, 3 patients came with pregnancy. 1st patient was operated 3 months back and she came with 5 months pregnancy (20 wk Fundal hight). On detain history examination she gave history of lactational amenorrhoea with house and vomiting off and on at the time of operation. Patient wants termination. Emcredil were installed and patient got aborted completely.

IIInd case gave history of one month 20 days amenorrhoea at the time of operation. Previous menstrual cycles were also prolong and she did not had any other symptoms. Patient came to hospital with 20 weeks pregnancy, wants termination. Emcredil were instilled and patient get aborted.

IIIrd patient gave history that period was due within one or two days during operation. But after operation she did not have period pregnancy continued in same luteal phase. That patient wants to continue pregnancy.



So there is no actual failure of laparoscopic ligation. But the easy pregnancy was missed in first two cases during clinical examination by some of junior doctor.

So the actual failure rate was nil

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\* C O N C L U S I O N \*  
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### C O N C L U S I O N

The present study was conducted at M.L.B. Medical College, Jhansi as well as in rural camps during one year period since May, 1984 to April, 1985, to evaluate the morbidity, mortality and failure rate of laparoscopic sterilization. Total 517 were operated and followed in this study. Out of these 452 cases were operated in rural camps and 65 cases were operated in post partum operation theatre. In camp setting all were interval cases while in post partum operation theatre 28 were M.T.P. cases and 37 were interval cases.

In brief it is concluded that

1. Incidence of complications was more in camps than in hospital cases.
2. Laparoscopic sterilization associated with medical termination of pregnancy were having more complications than interval cases due to softness of uterus.
3. Complication rate was more in rural population as compared to urban population. This is because of most of rural population belong to low socio-economic status, low educational status, poor

personal hygiene, they are usually malnourished, under weight, have skin infections, laxity of abdomen and divarication of recti.

4. Complication rate was higher in older age group and in multiparity.
5. No major complication like cardiac arrest, gas embolism and injury to major blood vessel, injury to bowel were seen in our study.
6. Many types of minor complications occurred which were mostly done by under training junior doctors. All these minor complications were easily tackled by senior surgeon.
7. These minor complication rate was more in camp setting 5.3% as compared to hospital setting 4.6%.
8. One case, which was started by some unexperienced doctor, haemorrhage take place but site of bleeding could not find out by laparoscop so laparotomy done by senior surgeon. Except this case none of other complication needed surgical intervanance.
9. In hospital, very limited number of complication occurred in comparison to camp cases. Which were mostly partaining to M.T.P. cases.

10. In camp setting, in 0.66% failed laparoscopy occurred because cases were not selected properly by P.H.C. doctors. While in hospital non of attempt failed.
11. No major anaesthetic complication were seen in our study. Minor complication like allergic reaction were only seen in 0.44% of camp cases. where sensitivity were not done previously.
12. On post operative followup within 1 wk, very minor type of complication seen in camp cases. None of them needed hospitalization. They all relieved by symptomatic treatment.
13. On long term followup, non of major complication was reported. Some menstrual irregularities were encountered. But on detail history. Most of them had previous history of menstrual disturbances.
14. None of the three failure of laparoscopic ligation were reported in our study. Cases reported, all were pregnant at the time of ligation in camps but they gave wrong history.
15. Target oriented and time limited programmes increased the risk of complication.

16. Most of minor complications were done by junior staff as they are inexperienced and under training. They all were handled immediately by senior experienced surgeon.
17. At last, we concluded that laparoscopic sterilization by falop ring is simple, safe and effective procedure. Most of minor complications reported were done by undertraining junior staff and they can be avoided by experience.

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